PATENT USSN: 10/763,339 Atty Dkt: 034047.003DIV1 (WRAIR 00-23A)

#### REMARKS

The Office action mailed 31 November 2007, has been received and its contents carefully noted. Claims 29-36 and 39 were pending, claims 31-34 and 36 were withdrawn from consideration, and claims 29, 30, 35 and 39 were rejected. Reconsideration in view of the following is respectfully requested.

## Rejection under 35 U.S.C. 103(a)

The Examiner rejected claims 29, 30, 35, and 39 under 35 U.S.C. 103(a) as being unpatentable over Doretti et al. in view of Magnotti et al. and further in view of Ellman et al. Specifically, the Examiner deemed that it would have been obvious to develop a handheld device with a biosensor to detect enzyme activity with all the requisite reagents for assays in the field.

Applicants respectfully submit that the cited art, alone or in combination, do <u>not</u> teach or suggest the claimed invention. Specifically, the cited art do not teach or suggest a means for determining the activity or the concentration of the protein using the <u>claimed</u> sensitivity coefficients for each substrate and for each protein in accordance with the present invention. The Examiner accepted our previous arguments indicating that the claimed sensitivity coefficients are not the same as the linear relationships disclosed in Doretti et al. since the rejection under 102(b) was withdrawn in view of Applicants remarks submitted 29 June 2007. The Examiner, however, appears to have overlooked the same claim language and arguments that were submitted in response to the rejection under 35 U.S.C. 103(a). In particular, the Examiner simply states that the prior arguments were not persuasive as the "inhibited dilutions and uninhibited dilutions of the protein' can be interpreted as different dilutions of the protein/substrate which is taught by Doretti (see page 10, Fig. 3)".

The sensitivity coefficient of the claimed invention is <u>not</u> the same as the linear responses provided in Doretti et al.\* The Examiner erroneously equates the <u>substrates</u> in Doretti et al. to be the same as the <u>proteins</u> in the inhibited dilutions of the claimed invention. In other words,

<sup>\*</sup> In Doretti et al., the "sensitivity" obtained from the linear relationship is to the substrate, i.e. the protein is constant and the substrate was varied (and presented in a linear fashion). Doretti's "sensitivity" is to the level of detection of the substrate, whereas in the present invention, the "sensitivity coefficients" describe the activity of a protein to a fixed substrate concentration in the presence and absence of an inhibitor. Just because linear relationships are used does not mean they are the same.

PATENT USSN: 10/763,339 Atty Dkt: 034047.003DIV1 (WRAIR 00-23A)

the Examiner erroneously deems that the different <u>substrate concentrations</u> discussed on page 10 and shown in Figure 3 of Doretti et al. are the same as the <u>inhibited protein dilutions</u> used to calculate the sensitivity coefficients as claimed. A substrate for a protein is NOT the same as the protein itself. The substrates and proteins of Doretti et al. and the claimed invention are not interchangeable with each other. Doretti et al. discloses the linear relationship between current response and different <u>substrate</u> concentrations. Doretti et al. does not teach or suggest the linear relationship between current response and different <u>substrate</u> concentrations. Specifically, Doretti et al. discloses the linear relationship between current response and different concentrations of choline <u>substrates</u> (butyrylthiocholine and butyrylcholine), not different concentrations (or inhibited dilutions) of <u>proteins</u> (cholinesterases). Thus, Doretti et al. does not provide a means for determining the activity or the concentration of a protein using a sensitivity coefficient for each substrate and for each protein as claimed.

Since Doretti et al. does not teach or suggest the claimed sensitivity coefficients, Doretti et al. does not teach or suggest the claimed means for determining the activity or concentration of a protein using the sensitivity coefficients of the present invention. Magnotti et al. and Ellman et al., alone or in combination, do not alleviate the deficiencies of Doretti et al. Specifically, the cited prior art do not teach or suggest using sensitivity coefficients which are determined with inhibited dilutions of proteins rather than different concentrations of substrates.

Therefore, the claimed invention is unobvious and the rejection under 35 U.S.C. 103(a) should properly be withdrawn.

Should the Examiner maintain that the linear relationships disclosed in Doretti et al. are the same as the linear relationships used to calculate the sensitivity coefficients of the present invention as claimed, Applicants respectfully request that the Examiner enter in the record an Official Notice indicating that the U.S. Patent & Trademark Office holds that a substrate for a protein is the same as the protein itself.

PATENT USSN: 10/763,339

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# Request for Rejoinder

Applicants respectfully request rejoinder of the withdrawn claims which ultimately depend on claim 29.

## Request for Interview

Either a telephonic or an in-person interview is respectfully requested should there be any remaining issues.

### CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Therefore, it is respectfully requested that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. 1.136(a), and any fees required therefor are hereby authorized to be charged to Deposit Account No. 210-380, Attorney Docket No. 034047.003DIV1 (WRAIR 00-23).

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Date: 12 December 2007

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